PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
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ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 02 December 1999 (02.12.99)	
International application No. PCT/AU99/00310	**Applicant's or agent's file reference** 2170180/JMS
International filing date (day/month/year) 27 April 1999 (27.04.99)	**Priority date** (day/month/year) 28 April 1998 (28.04.98)
Applicant CHANDLER, Howard, Milne	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

22 November 1999 (22.11.99)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

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Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

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Form PCT/IB/331 (July 1992)

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PATENT COOPERATION TREATY

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NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

SLATTERY, John, M.
Davies Collison Cave
1 Little Collins Street
Melbourne, VIC 3000
AUSTRALIE

Date of mailing (day/month/year)
12 July 2000 (12.07.00)

Applicant's or agent's file reference
2170180/JMS

IMPORTANT NOTIFICATION

International application No.
PCT/AU99/00310

International filing date (day/month/year)
27 April 1999 (27.04.99)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address	State of Nationality	State of Residence
	US	US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [X] the name [X] the address [X] the nationality [X] the residence

Name and Address	State of Nationality	State of Residence
ENTERIX, INC. 348 US Route One Falmouth, ME 04105 United States of America	US	US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:
New applicant for all states except the US. CHANDLER, Howard, Milne should now be listed as applicant/inventor for US only.

4. A copy of this notification has been sent to:

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[ ] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer I. Britel
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003405303

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PA ENT COOPERATION TREAT

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

SLATTERY, John, M.
Davies Collison Cave
1 Little Collins Street
Melbourne, VIC 3000
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Date of mailing (day/month/year)
22 January 2001 (22.01.01)

Applicant's or agent's file reference
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IMPORTANT NOTIFICATION

International application No.
PCT/AU99/00310

International filing date (day/month/year)
27 April 1999 (27.04.99)

1. The following indications appeared on record concerning:
[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address

State of Nationality | State of Residence

Telephone No.

Facsimile No.

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:
[X] the person [X] the name [X] the address [X] the nationality [X] the residence

Name and Address
ENTERIX INC.
348 US Route One
Falmouth, ME 04105
United States of America

State of Nationality: US | State of Residence: US

Telephone No.

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:
New applicant for all designated states except US. CHANDLER, Howard, Milne should now be listed as applicant/inventor for US only.

4. A copy of this notification has been sent to:
[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

Authorized officer
I. Britel
Telephone No.: (41-22) 338.83.38

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SAMPLE COLLECTION METHOD

FIELD OF THE INVENTION

This invention relates to a method for collecting a sample for subsequent use in the detection of an analyte in the sample. In one particular embodiment, this invention relates to a method for sampling faecal material for the purposes of subsequent detection in the sample of occult blood or one or more other indicators of a pathological condition.

The present invention also extends to an assay kit which is particularly suitable for the purposes of detection in a sample derived from faecal material of occult blood or one or more other indicators of a pathological condition.

BACKGROUND OF THE INVENTION

A well known and widely-used clinical reagent for the detection of occult blood in a sample, particularly a faecal sample, is guaiac (also known as gum guaiac or resin guaiac). When used in association with an appropriate developer solution, guaiac provides a colorimetric assay system for detecting haemoglobin in the sample. Such tests are commercially available, for example, Hemoccult II and Hemoccult II Sensa (SmithKline Diagnostics, San Jose, California, USA).

Prior Australian Patent No. 665956 (International Patent Application No. PCT/US92/04425) notes that among the many analytical systems used for detection and/or determination of analytes, particularly analytes of biological interest, are chromatographic assay systems. Among the analytes of biological interest frequently assayed with such systems are:

1. hormones, such as human chorionic gonadotropin (hCG), frequently assayed as a marker of human pregnancy;
2. antigens, particularly antigens specific to bacterial, viral, and protozoan pathogens, such as *Streptococcus*, hepatitis virus, and *Giardia*;

3. antibodies, particularly antibodies induced as a result of infection with pathogens, such as antibody to the bacterium *Helicobacter pylori* and to human immunodeficiency virus (HIV);
4. other proteins, such as haemoglobin, frequently assayed in determinations of faecal occult blood, an early indicator of gastrointestinal disorders such as colon cancer;
5. enzymes, such as aspartate aminotransferase, lactate dehydrogenase, alkaline phosphatase, and glutamate dehydrogenase, frequently assayed as indicators of physiological function and tissue damage;
6. drugs, both therapeutic drugs, such as antibiotics, tranquillisers and anticonvulsants, and illegal drugs of abuse, such as cocaine, heroin, and marijuana; and
7. vitamins.

Such chromatographic systems are frequently used by physicians and medical technicians for rapid in-office diagnosis and therapeutic monitoring of a variety of conditions and disorders. They are also increasingly used by patients themselves for at-home monitoring of such conditions and disorders.

Among the most important of such chromatographic systems are the "thin layer" membrane-based systems in which a solvent moves as a solvent front across a thin, flat absorbent medium (e.g., nitrocellulose membrane). Among the most important of tests that can be performed with such thin layer systems are immunoassays, which depend on the specific interaction between an antigen or hapten and a corresponding antibody. The use of immunoassays as a means of testing for the presence and/or amount of clinically important molecules has been known for some time.

Chromatographic techniques used in conjunction with immunoassays include a procedure known as immunochromatography. In general, this technique uses a disclosing reagent or particle that has been linked to an antibody to the analyte to be

assayed, forming a conjugate. This conjugate is then mixed with a specimen and, if the analyte to be assayed is present in the specimen, the disclosing reagent-linked antibodies bind to the analyte to be assayed, thereby giving an indication that the analyte to be assayed is present. The disclosing reagent or particle can be identifiable by colour, magnetic properties, radioactivity, specific reactivity with another molecule, or another physical or chemical property. The specific reactions that are employed vary with the nature of the analyte being assayed and the sample to be tested.

The present invention is particularly, but not exclusively, directed to collection of samples derived from faecal material for occult blood detection, for example in screening for colorectal cancer. As previously described, guaiac testing provides a colorimetric assay system for detection of haemoglobin in a sample, however because of the large number of false positives obtained in guaiac testing, in screening programs the use of two or three guaiac tests has been recommended, confirmed when positive by an immunological test for human haemoglobin (Favennic L., Kapel N., Meillet D., Chochillon C. and Gobert J.G., *Annales de Biologie Clinique*, **50**(5):311-3, 1992). More recently, a combination of guaiac and immunological testing has been suggested (Allison, J.E., Tekawa, I.S., Ransom, L.J. and Adrian, L.L. *N. Engl. J. Med.*, **334**:155-9, 1996).

It is an object of the present invention to provide a sample collection method which is simple and economic, and which enables subsequent detection and/or determination of analyte in the sample to be readily carried out, for example using a guaiac test, and/or an immunochromatographic or other immunodiagnostic procedure.

SUMMARY OF THE INVENTION

In accordance with the present invention, there is provided a method for collecting a sample derived from faecal material, comprising contacting the faecal material with a fluid and subsequently collecting a sample of the fluid with a brush or

brush-like device having flexible or semi-flexible bristles, wherein the sample of the fluid is collected within the bristles of the brush or brush-like device.

Preferably, the fluid is water.

The term "brush" as used herein is used to denote device comprising a stem or handle, usually elongate, and a clump, bunch or group of bristles, hair or other similar flexible or semi-flexible elongate strands, laminar flaps or the like attached to the stem or handle. The term "brush-like device" is used herein to denote a device which is similar to a brush in that it includes a bunch, clump or group of bristles, hair or other similar flexible or semi-flexible elongate strands, laminar flaps or the like. Whilst reference is made throughout the present specification to the collection of a sample within the bristles of a brush or brush-like device, it is to be understood that the reference to "bristles" is used to include the hairs or other similar flexible or semi-flexible elongate strands, laminar flaps or the like of a brush or brush-like device.

Preferably, the bristles of the brush or brush-like device will have a length of about 0.2 to 3 cm long, more preferably a length of 1 to 2 cm.

In another embodiment, the present invention also extends to an assay kit for testing faecal material which comprises a sample collection device which is a brush or brush-like device having flexible or semi-flexible bristles, together with means for detection of an analyte in a sample derived from faecal material.

Such an assay kit is particularly suited for use in detection of occult blood in a sample derived from faecal material. The detection of occult gastrointestinal bleeding is a common method for screening for colorectal cancer. Commonly referred to as the faecal occult blood (FOB) test, a variety of formats are known in the art (see, for example, US Patent Nos. 3996006; 4225557; 4789629; 5064766; 5100619; 5106582; 5171528; 5171529; and 5182191). The majority of test formats are based

on the chemical detection of the heme groups present in faecal material as a breakdown product of blood. In such tests, the pseudoperoxidase nature of the heme group is used to catalyse a colorimetric reaction between an indicator dye and peroxide. The oxygen sensitive dye can be gum guaiac, orthodianisidine, tetramethylbenzidine, or the like, with guaiac being preferred.

The means for detection of an analyte in a sample which is incorporated into an assay kit as described above may, for example, be means for carrying out a guaiac test for the detection of occult blood in the sample. Alternatively, or additionally, the means for detection of an analyte in a sample may be means for detection of occult blood (or other diagnostic antigens) in the sample by means of a chromatographic procedure, particularly by an immunochromatographic or other immunodiagnostic procedure which is well known in the art. Suitable immunochromatographic procedures are described, by way of example, in US Patent Nos. 5591645 and 5622871, the disclosures of which are incorporated herein by reference.

Whilst the present invention is particularly useful in FOB testing as described in detail herein, it is to be understood that the method and assay kit as broadly described herein may be used in sampling faecal material and subsequent testing of the sample to detect the presence of one or more other indicators of a pathological condition, for example, tumour-derived antigens, in addition to or instead of FOB testing.

Throughout this specification, unless the context requires otherwise, the word "comprise", and or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

DETAILED DESCRIPTION OF THE INVENTION

In the most preferred embodiment, the present invention relates to the use of a brush as a device for obtaining a sample derived from faecal material, and particularly stool, in a fluid such as water, particularly for the detection of occult blood as an indicator of colorectal cancer (CRC) or its precursor conditions.

Most existing faecal occult blood tests (FOBTs) use a sampling stick or paddle to take smears directly from the surface of a collected faecal sample. European Patent Application No. EP 0 727653 discloses the use of a brush device having stiff bristles to collect a sample from the surface of faecal material directly on the bristles. Many CRCs or their precursors (e.g. adenomas > 1cm), bleed into the lumen of the small intestine. As these malignancies arise as protrusions from the wall of the intestine they make contact with the surface of the stool in their region of contact as the stool passes that point. The blood, therefore, may not be evenly distributed through or over the stool. As a result, existing tests that rely on surface sampling of the stool may or may not sample from that portion of the stool where blood is present.

If the stool or other faecal material is sampled in a fluid, for example, when it is in the water of the toilet bowl, there is a better opportunity to gain a representative sampling of the whole stool. This is particularly the case where a small brush (e.g. a small artist's paint brush having bristles about 1 to 2 cm in length) is used for sampling. A brush may be used to "paint" the surface of the stool so as to displace any blood on the surface of the stool into the water surrounding the stool. The flexible or semi-flexible bristles of the brush will be relatively "open" during this brushing and sampling process, but will "close" as the brush is withdrawn from the water, thereby keeping a sample of the water (and any blood contained therein), surrounding the stool within the interstitial spaces of the bristles. This sample may then be transferred to a suitable assay device for subsequent testing.

By way of contrast, if an absorbent sampling device, such as a swab, was used for sampling, water would infiltrate the fibre windings of the swab on its first contact with the water in the toilet bowl. In this case, there would be little chance of effective displacement of the infiltrated water by any blood-containing water in the vicinity of the stool, and as a result the sampling procedure would not effectively sample any such blood-containing water.

Alternatively, if a solid sampling device such as a solid sampling stick or paddle, or a loop or barbed probe was used, the water sampled from around the stool would be lost as the device was withdrawn through the water of the bowl, and once again the sampling procedure would not effectively sample any blood-containing water.

A further advantage which is obtained by the use of a brush or brush-like sampling device in accordance with the present invention is that the fluid sample collected within the bristles of the sampling device as described above is collected in a semi-quantitative manner, in that the amount of fluid held within the interstitial spaces of the bristles of the sampling device will be a reasonably constant amount for any particular size and configuration of the sampling device.

As described above, an important feature of the sampling device is that the bristles of the device, as defined above, are flexible or semi-flexible. This enables the device to be used to obtain a sample of fluid surrounding the faecal material into which any occult blood on or at the surface of the faecal material has been dispersed, instead of attempting to obtain a sample directly from the surface of the faecal material where it may only be present in isolated locations, and accordingly where there is a risk that any sample taken directly from the surface of the faecal material may not be taken from a location where any blood is present.

As previously described, colorectal cancers and adenomas often bleed into the lumen of the large bowel. Initially, only a small, localised amount of blood leakage may

occur, leading to isolated spots or areas of blood occurring on the surface of faecal material in the large bowel which will be exposed to the blood first. It is not unreasonable to assume that much of this blood will remain on the surface of this faecal material after it is passed. Similarly, almost all colorectal cancers and all adenomas occupy only a small portion of the diameter of the large bowel. Therefore, it is also likely that the blood from such lesions will be striped along the faecal material. If this is the case, the brush method of the present invention for sampling faecal material will have an advantage over traditional FOBT sampling methods because the sampling method of the present invention takes a more representative sample than that of the traditional methods.

Further features of the present invention are more fully described in the following Example(s). It is to be understood, however, that this detailed description is included solely for the purposes of exemplifying the present invention, and should not be understood in any way as a restriction on the broad description of the invention as set out above.

EXAMPLE 1

The suitability of a brush for sampling blood in water has been shown to be effective by several means:

1. Blood (10 µL) was added to water (50 mL) in a beaker. After the blood settled to a discrete drop at the bottom of the beaker, a brush (#5, LiFung, Hong Kong) was first used to sample the surface water from the beaker. This sample tested negative in a faecal occult blood (FOB) test (Enterix). After mixing the contents of the beaker, a second, similar brush was shown to be capable of selectively sampling sufficient of the blood to be detected in a similar FOB test.

2. A stool sample was injected with blood (50 µL) so that the blood was sequestered within a crevice in the stool. The stool was added to a toilet bowl and brushes as described above were used to sample:

(a) The water of the bowl.

(b) The water surrounding the stool after the surface of the stool was "brushed".

When tested in FOB tests (Enterix), samples (a) tested negative for blood, whereas samples (b) tested positive. In this experiment it may be expected that the sequestered blood would have been missed by conventional sampling of the stool surface with a stick or paddle.

3. Table 1 below shows the results of a series of experiments to test the effectiveness of sampling of stool samples with a brush as described above. Blood was added directly to normal stool samples, before or after the deposition of the stools into a toilet bowl. Normal stools and the bowl water before stool addition were also sampled. In each case samples collected by the brush method were tested for the presence of blood by an FOB test (Enterix).

TABLE 1

FOB Test Results	Bowl Water	Normal stool (i.e. no addition)	25 µL blood added	50 µL blood added	100 µL blood added
No. positive	-	-	4/4	15/15	27/27
No. negative	2/2	15/15	-	-	-

As shown in the Table, all toilet bowl water and normal stool samples tested negative in the FOB test, whereas all samples with added blood (≥ 25 µL) gave a positive test result. These results compare favourably with the sensitivity and

specificity data reported with tests that use direct stool sampling with a sampling stick (Rosen, P., Knaai, J. and Samuel, Z. *Dig. Dis. Sci.*, **42**(10):2064-71, 1997).

EXAMPLE 2

The aim of this study was to determine if the sampling method of the present invention is more capable of detecting significant quantities of blood than a traditional method of FOBT sampling when the blood is striped along one side of the surface of a stool.

Methods

Ten faecal samples were collected from three individuals and spiked with blood to a concentration of 0.5 milligrams of haemoglobin per gram faeces. Spiking was achieved by spotting the blood along the surface of the stool in a stripe.

Five spiked stools were tested both by the method of the present invention (EnterixOBT) and by FlexSureOBT (Beckman Coulter Personal Care Diagnostics, Palo Alto, California, U.S.A.). The samples for testing were collected as per the manufacturer's instructions for each test exactly as if the person had been defecating directly into the toilet bowl (EnterixOBT) or into a paper saddle (FlexSureOBT). In the EnterixOBT test, the sampling device is a brush (LiFung, Hong Kong) having a plastic stem or handle (approx. 185 mm length, 4-6 mm diameter) and flexible bristles (approx. 15 mm length). The sampling device for the FlexSureOBT test is a solid paddle or "popsicle" stick. To avoid bias, sampling for each test was standardised. and blinded For EnterixOBT, samples were collected by five brush strokes of the upright surface of the stool. Where loose stools were concerned, the brush was swirled around the stool five times. For FlexSureOBT, sampling was carried out as per manufacturer's instructions at random points on the stool.

All tests were developed three-four days after sampling and all tests were read by two independent readers. The results are shown in Table 2 below.

Results

TABLE 2 Test results for stripe-spiked stool samples.

	EnterixOBT (n=5)		FlexSureOBT (n=5)	
	Reader A	Reader B	Reader A	Reader B
Positive	5	5	1	1
Negative	0	0	4	4

Discussion

Although the number of samples tested in this study is small, EnterixOBT appears to be able to detect a significant quantity of blood better than FlexSureOBT when the blood is striped along the surface of the stool. This difference is presumably due to the different methods of sampling employed by each test. As a result, EnterixOBT appears to have a clear advantage over FlexSureOBT in terms of the clinical detection of occult blood on faecal material, for example, in the detection of colorectal neoplasia.

Persons skilled in this art will appreciate that variations and modifications may be made to the invention as broadly described herein, other than those specifically described without departing from the spirit and scope of the invention. It is to be understood that this invention extends to include all such variations and modifications.

CLAIMS:

1. A method for collecting a sample derived from faecal material, comprising contacting the faecal material with a fluid and subsequently collecting a sample of the fluid with a brush or brush-like device having flexible or semi-flexible bristles, wherein the sample of the fluid is collected within the bristles of the brush or brush-like device.

2. A method according to claim 1, wherein the fluid is water.

3. A method according to claim 1 or claim 2, wherein the bristles of the brush or brush-like device have a length of from 0.2 to 3 cm, preferably from 1 to 2 cm.

4. A method according to claim 1, wherein the sample collected with the brush or brush-like device is transferred to an assay device for subsequent testing.

5. A method according to claim 4, wherein said assay device is a test device for detecting occult blood or one or more other indicators of a pathological condition in the faecal material from which the sample is derived.

6. A method for the detection of occult blood in faecal material, which comprises the steps of:

   i. contacting the faecal material with water to disperse any blood present in or on the faecal material into the water,

   ii. subsequently collecting a sample of the water with a brush or brush-like device having flexible or semi-flexible bristles, wherein the sample of the water is collected within the bristles of the brush or brush-like device; and

   iii. detecting the presence of blood, if any, in the sample.

7. A method according to claim 6, wherein the presence of blood, if any, in a sample is detected by means of a guaiac test.

8. A method according to claim 6, wherein the presence of blood, if any, in the sample is detected by means of an immunochromatographic test.

9. An assay kit for testing faecal material, which comprises a sample collection device which is a brush or brush-like device having flexible or semi-flexible bristles, together with means for detection of an analyte in a sample derived from the faecal material.

10. A kit according to claim 9, wherein the bristles of the brush or brush-like device have a length of from 0.2 to 3 cm, preferably from 1 to 2 cm.

11. A kit according to claim 9, wherein said means for detection is a test device for detecting occult blood or one or more other indicators of a pathological condition in the faecal material from which the sample is derived.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00310

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: G01N 1/10, 33/72, C12Q 1/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC : G01N and C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU : IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT & JAPIO : G10N or C12Q and (fecal or feces or faeces) and occult ( ) blood

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0727653 A (WAKO PURE CHEMICAL INDUSTRIES, LTD) 21 August 1992 see whole document	1-11
A	EP 0281251 A (INTERNATIONAL IMMINOASSAY LABORATORIES, INC.) 7 September 1988 see whole document	1-11

☐ Further documents are listed in the continuation of Box C

☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
10 May 1999

Date of mailing of the international search report
14 MAY 1999

Name and mailing address of the ISA/AU
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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU 99/00310

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
EP	0727653	JP	8285845	US	5882942
EP	0281251	JP	63271160	US	5198365

END OF ANNEX

October 27, 2000

THIS WILL ACKNOWLEDGE RECEIPT OF:

U.S. National Stage Patent Application Transmittal; Specification (pgs. 1-11); Claims (pgs. 12-13); Abstract of the Disclosure (pg. 14); and Express Mail Label EK257451949US.

Applicant(s): Howard Milne Chandler
Title: SAMPLE COLLECTION METHOD

Docket No.: 0141-2004

Date Received by PTO:

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2170180/JMS:ETC	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. **PCT/AU 99/00310**	International filing date *(day/month/year)* 27 April 1999	Priority Date *(day/month/year)* 28 April 1998
International Patent Classification (IPC) or national classification and IPC **Int. Cl.**[6] G01N 1/10, 33/72, C12Q 1/28		
Applicant CHANDLER, Howard Milne		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

Date of submission of the demand 22 November 1999	Date of completion of the report 29 November 1999
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **ALBERT S. J. YONG** Telephone No. (02) 6283

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU 99/00310

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , filed with the letter of .

[ ] the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , filed with the letter of .

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , filed with the letter of .

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , filed with the letter of .

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-11	YES
	Claims	NO
Inventive step (IS)	Claims 1-11	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-11	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

CITATIONS

EP 0727653A
EP 0281251A

NOVELTY (N) AND INVENTIVE STEP (IS)

Claims 1-11: The claimed invention relates to a brush-like device for sampling faecal material for the purpose of detecting occult blood.

EP 0281251 discloses a sampling device having a spatula dimensioned to take a selected amount of stool and dispersing it in a selected volume of liquid. However, it does not teach the sampling of a fluid that has been in contact with the faecal material.

EP 0727653 discloses the use of a brush device having stiff bristles to collect a sample from the surface of faecal material. However, the stiff bristles do not allow for the collection of a sample of water (and any blood contained therein) surrounding the stool.

INDUSTRIAL APPLICABILITY

The claimed invention has applications in the field of analytical systems.